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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,297	11/25/2003	Thomas C. Sudhof	UNI919/4-006US/75009	7082
21586	7590	02/27/2006	EXAMINER	
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760			CHERNYSHEV, OLGA N	
		ART UNIT		PAPER NUMBER
				1649

DATE MAILED: 02/27/2006

12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/721,297	SUDHOF ET AL.
	Examiner Olga N. Chernyshev	Art Unit 1649

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-48 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-48 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date. _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

***Formal matters***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, drawn to a method of identifying agents that modulate cleavage of APP by contacting a chimeric molecule with  $\beta$ -secretase, classified in class 435, subclass 23, for example.
  - II. Claims 12-18, drawn to a method of identifying agents that modulate cleavage of APP by contacting a chimeric molecule with  $\gamma$ -secretase, classified in class 435, subclass 23, for example.
  - III. Claims 19-21, drawn to a method of identifying agents that modulate cleavage of APP by  $\beta$ -secretase involving APLP, classified in class 435, subclass 7.2, for example.
  - IV. Claims 22-29, drawn to a polypeptide substrate comprising APP  $\beta$ -secretase site and encoding nucleic acids, classified in class 435, subclass 69.1, for example.
  - V. Claims 30-37, drawn to a polypeptide substrate comprising APLP  $\beta$ -secretase site and encoding nucleic acids, classified in class 435, subclass 69.1, for example.

VI. Claims 38-48, drawn to a method of identifying agents that modulate cleavage of APP like proteins, classified in class undetermined, subclass undetermined, for example.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions. The instant specification does not disclose that these methods would be used together. The methods of Groups I, II, III and VI are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for the claimed methods differ significantly for each of the materials. Searching the inventions of Groups I, II, III and VI together would impose serious search burden. The inventions of Groups I, II, III and VI have a separate status in the art as shown by their different classification. Moreover, in the instant case, the searches for each claimed method are not coextensive. Prior art which teaches a method of identifying agents that modulate the cleavage of APP would not necessarily be applicable to the methods of identifying agents that specifically modulate cleavage of APLP, for example. For these reasons the Inventions I, II, III and VI are patentably distinct.

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4. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions IV and V are independent and distinct, each from each other, because they encompass products which possess characteristic differences in structure and function and each has independent utility that is distinct for each invention which cannot be exchanged. Each of these products are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art chemical compounds. Because these products are structurally distinct molecules, the search of each of these products is not coextensive. In cases as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature as well as in electronic databases. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, which also includes searching different electronic databases, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above

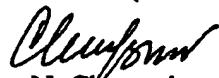
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policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

December 8, 2005